

### REMARKS

Claims 1-18 and 22 have been canceled as directed to non-elected inventions. Claim 19 has been amended to describe the polyketide synthase in the terms set forth in claim 1 of the parent application as issued in U.S. 6,753,173. Claims 20 and 21 are unchanged; claim 23 has been added for those instances where the modules are unmodified from those that occur in nature. Claim 24 corresponds to claim 2 of the '173 patent; claim 25 contains the limitations of claims 3-14 of '173 in the alternative. New claims 26-31 are the corresponding claims to those of 19-21 and 23-24 related to the inter-molecular linker (ERL) rather than in the intra-molecular linker (RAL). Claim 26 incorporates the language describing the hybrid PKS from claim 15 of the issued patent. Claims 27 and 28 correspond to claims 20 and 21 herein; claim 29 corresponds to claim 23 herein; claim 30 corresponds to claim 16 of the issued patent and claim 31 corresponds to claims 17-28 taken in the alternative. No new matter has been added and entry of the amendment is respectfully requested.

### Formal Matters

Applicants appreciate the acknowledgement of priority, the adequacy of the Information Disclosure Statement, and compliance with sequence rules. The title has been amended in accordance with the suggestion of the Office and amendments to the specification have been made in order to correct the informalities noted by the Office. The objections to the claims are believed moot due to the present amendment.

### The Rejection Under 35 U.S.C. § 112, ¶ 2 and Terminal Disclaimer

As noted in the Office action, these rejections are overcome by using the language found in the claims describing the hybrid PKS in the parent as issued in U.S. 6,753,173. This language has

been adopted in its entirety and it is therefore believed that the rejection under 35 U.S.C. § 112, ¶ 2, is overcome, as kindly suggested by the Office.

Applicants agree that a terminal disclaimer is appropriate and a terminal disclaimer with respect to this issued patent is enclosed.

#### The Rejection Under 35 U.S.C. § 112, ¶ 1

Applicants believe that the amendments to the claims overcome this rejection for the reasons a similar rejection was overcome in the parent application. Applicants greatly appreciate agreement with this as confirmed in a telephone interview with Examiner Kerr on 19 November 2004. To the extent necessary, the arguments set forth with respect to a similar rejection in parent application 09/500,747 are incorporated herein by reference. However, as agreed in the telephone interview, the amended language itself overcomes this rejection.

#### The Rejection Under 35 U.S.C. § 102

Claims 19-21 were rejected under 35 U.S.C. § 102(b) as anticipated by McDaniel, *et al.*, *Chem & Biol* (1997) 4:667-674. The Office refers to Figure 6 and the disclosure of KOS011-58 in which module 2 of the 6-dEB PKS is modified by replacing catalytic domains for AT, ketoreductase, and ACP with corresponding domains from rapamycin. The RAL of 6-dEB between modules 1 and 2 remains in the construct, as does the ERL between modules 2 and 3.

It is believed that such replacements of catalytic domains, if incomplete, do not result in hybrids that read on claims which require that the first and second extender modules be from different polyketide synthases. Despite the replacement of several catalytic domains, applicants regard module 2 as derived from the same polyketide synthase as module 1. Under this interpretation, McDaniel does not anticipate the invention as now claimed.

It is apparent that McDaniel does not anticipate claims 23 and 26 which require that the extender modules be those which occur in nature, or those specific embodiments in claims 25 and 31.

Thus, applicants believe that under a fair interpretation of the claims as amended, McDaniel does not anticipate nor render the claimed invention obvious as the claimed invention resides in the discovery that the appropriate intramolecular or intermolecular linker is necessary to facilitate the synthesis of polyketides. Therefore, this basis for rejection may also be withdrawn.

**CONCLUSION**

The claims have been amended to conform the language describing the hybrid modular polyketide synthase to conform to that of issued claims 1 and 15 from the parent. Accordingly, as agreed by the Examiner, outstanding rejections over 35 U.S.C. § 112 are overcome. Under the claim construction offered by applicants, it is believed that the rejection for anticipation over McDaniel is overcome as well. Accordingly, applicants respectfully request that claims 19-21 and 23-31 be passed to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 300622004620.

Respectfully submitted,

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